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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,604	05/31/2000	Andrew J. Dannenberg	CRF D-2165	9421

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	PAPER NUMBER
1617	10

DATE MAILED: 03/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/554,604	Applicant(s) DANNENBERG, ANDREW J.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 17* is/are pending in the application.

4a) Of the above claim(s) *7-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of applicant' amendments and remarks submitted January 7, 2002 is acknowledged.

Claim Rejections 35 U.S.C. 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, for reasons set forth in the prior office action

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-2 are rejected under 35 U.S.C. 102(a) as being anticipated by Gregory et al. (WO 97/297776).

3. Gregory et al. teaches a method for treating a patient with organ transplantation, (liver, heart, and kidney), or patient with autoimmune disease, or inflammatory disease(e.g., biliary cirrhosis), comprising administering to the patient a cyclooxygenase-2 inhibitor employed herein, without administration of leukotreneB4 receptor antagonist. See, particularly, the claims, and page 10, lines 10-18.

Claim Rejections 35 U.S.C. 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-6 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gregory et al. (US Patent 6, 172,096), in further view of Tally et al. (US Patent 5,643,933, IDS).

6. Gregory et al. teaches a method for treating a patient with organ transplantation, (liver, heart, and kidney), or patient with autoimmune disease, or inflammatory disease (e.g., biliary cirrhosis), comprising administering to the patient a cyclooxygenase-2 inhibitor employed herein, See, particularly, the claims, and column 5, lines 42-67. Gregory et al. further teaches that the method is generally known to be useful for treating immune related disease including biliary cirrhosis. See, column 5, lines 42 bridging column 6, line 16.

7. Gregory et al. does not teach expressly the treatment of liver diseases listed herein by the method therein.

1. However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the compounds herein for treating hepatitis disease because those compounds are known generally to be useful for treating inflammatory diseases and is also known to be useful for treating liver related diseases. Regarding claim 6 and 17, which define the cox-2 inhibitor also inhibits the synthesis of cox-2 protein, note it is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed

to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Additionally, where the patent Office has reason to believe that a functionally limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to requires the applicant to prove that the subject matter shown to be in the prior art does not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103. Further, claim 6 and 17 are obvious for reasons discussed above, in further view of Tally. Tally teaches that the agent employed in claim 6, is known to be similarly useful as the compounds employed in claims 4 and 5, i.e., as cox-2 inhibitor. See, particularly, column 2, line 15 bridging column 3, line 26.

2. Applicants' amendments and remarks submitted January 7, 2002 have been fully considered, but are not persuasive for reasons discussed below.

3. Applicants assert that the 112 rejection is improper. The examiner disagree. The disclosure in the specification may not be read in to the specification. The agent employed in claim 6, 'inhibitor of cyclooxygenase-2 directly inhibits the enzyme cyclooxygenase –2 and also inhibits the synthesis of cyclooxygenase –2 protein' encompass any compound may possess such properties, not limit to those disclosed in the specification. There is no well-established

definition regarding what type of compounds would be 'inhibitor of cyclooxygenase-2 directly inhibits the enzyme cyclooxygenase –2 and also inhibits the synthesis of cyclooxygenase –2 protein'. As stated in the prior office action, A person of ordinary skill in the art would have been required to perform undue experimentation to use claimed invention, particularly, to identify those 'inhibitor of cyclooxygenase-2 directly inhibits the enzyme cyclooxygenase –2 and also inhibits the synthesis of cyclooxygenase –2 protein' within claimed scope.

4. The argument regarding the rejection under 35 U.S.C. 102 and 103 are moot in view of the new ground of rejection.

5. Applicants' rebuttal arguments that NSAIDs are well known for their hepatoxicity and therefore are know in the art for not suitable for treating liver disease have been considered, but are not persuasive. Since COX-2 inhibitors are known for their selectively inhibiting COX-2, which is different from the conventional NSAIDs, which inhibit both COX-1 and COX-2. It is also known that COX-1 expression dominates normal tissues while COX-2 expression is found in inflammatory tissue. One of ordinary skill in the art would have reasonably expected that selective COX-2 inhibitors would be not hepatoxic like conventional NSAIDs. See, e.g., Seibert et al. (CAPLUS Abstract, AN 1998 :369098).

6. Applicants' assertion that Talley (5,643,993) does not teaches the compounds employed in claim 6 is incorrect. Talley teaches the general structures which encompass the compounds disclosed in page 18 of the specification. Specifically, Talley state, within the structure given in column 2, 'Ar is selected from aryl and heteroary, wherein Ar is optionally substituted with one or two substituents selected from halo, hydroxyl, amino, nitro, cyano, carbamoyl, alkyl, alkenyloxy, alkoxy,...' see column 3, lines 21-25.

7. Regarding the remarks about the inherency, note the examiner has not seen any factual evidence showing that COX-2 inhibitor employed by Gregory do not have the function as defined in claim 6.

8. Nothing unobvious is seen in the claimed invention.

9. This application contains claims 7-11 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

S. Wang

Shengjun Wang

AU 1617
3-13-2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200